

REMARKS

Applicants thank the Examiner for the detailed Office Action dated 21 February 2008. Applicants respectfully request reconsideration of the present application in view of the reasons that follow.

Claims 35-39, 41-49, 51-73, and 76-77 were pending in the application. Claims 35, 37, 49, 55, 63, 67, and 71 are currently being amended. After amending the claims as set forth above, claims 35-39, 41-49, 51-73, and 76-77 are now pending in this application.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks are primarily focused on the rejections applied to the independent claims (*i.e.*, claims 35, 37, 44, 49, 55, 63, 67, and 71) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicants expressly reserve the right to argue the patentability of the dependent claims separately in any future proceedings.

Structural Limitations in a Method Claim

As a preliminary matter, Applicants challenge the Examiner's assertion that structural limitations should only be given weight in a method claim when "the recited structural limitations affect the method in a manipulative sense" (relying on *Ex parte Pfeiffer*, 1962 C.D. 408 (1961). Office Action dated 21 February 2008, page 5. The governing legal principle is that "all limitations must be considered and [] it is error to ignore specific limitations distinguishing over the references." *In re Boe*, 505 F.2d 1297, 1299, 184 USPQ 38, 40 (CCPA 1974).

Applicants further note that the Board of Patent Appeals and Interferences has considered the same argument four times since 1997 and has rejected it in each case. See Ex parte Tuma at <http://des.uspto.gov/Foia/RetrivePdf?system=BPAI&flNm=fd2006230809-26-2006>; Ex parte Holderness et al. at <http://des.uspto.gov/Foia/RetrivePdf?system=BPAI&flNm=fd980553>; Ex parte Zeigler et al. at <http://des.uspto.gov/Foia/RetrivePdf?system=BPAI&flNm=fd962718>; Ex parte Kirkland at <http://des.uspto.gov/Foia/RetrivePdf?system=BPAI&flNm=fd970172>. In particular, the Examiner has found that such an argument is inconsistent with binding Federal Circuit precedent in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Boe*, 505 F.2d 1297, 1299, 184 USPQ 38, 40 (CCPA 1974).

For these reasons, Applicants submit that it is improper for the Examiner to ignore any structural limitations in any of the claims.

Claim Rejections – 35 U.S.C. § 102

Independent Claims 35, 37, 44, and 55 over Nash et al.

On pages 2-3 of the Office Action, independent 35, 37, 44, and 55 and various dependent claims were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,662,681 to Nash et al. Applicants respectfully traverse the rejection. Nash et al. does not identically disclose the subject matter recited in independent claims 35, 37, 44, or 55.

Independent claims 35 and 37

Nash et al. does not identically disclose the methods recited in independent claims 35 and 37, each of which requires, among other things, a “multi-level nest” that comprises a “first surface contacting the anchor” and a “second surface spaced from the anchor in a direction

radially inward relative to the carrier tube," wherein "the first surface and the second surface are part of an **outer surface** of the carrier tube." In the Office Action, the Examiner asserts that the second surface recited in claims 35 and 37 is the inner lumen surface of carrier tube 102 in Nash et al. Claims 35 and 37 have been amended to recite that the second surface is part of an outer surface of the carrier tube. Accordingly, the Examiner's argument is no longer applicable.

Independent claim 44

Independent claim 44 recites that the carrier tube includes an outer surface and the "**outer surface includ[es]** a first surface portion that is in contact with the anchor and a **second surface portion** that is adjacent to the anchor and recessed in the carrier tube relative to the first surface portion." The inner lumen surface of the carrier tube of Nash et al. does not qualify as the second surface portion because claim 44 explicitly recites that the outer surface of the carrier tube includes the second surface portion. Thus, Nash et al. does not show all of the limitations recited in claim 44.

Independent claim 55

Independent claim 55 recites that the carrier tube includes an outer surface and a "recess extending radially further into the outer surface of the carrier tube than the first surface portion." The inner lumen surface of the carrier tube of Nash et al. fails to qualify as the recited recess. Nothing else in Nash et al. qualifies as the recited recess.

For the above reasons, Applicants respectfully submit that independent claims 35, 37, 44, and 55 and the claims which are dependent thereon are not anticipated by the cited reference and are patentable.

Independent Claim 37 over Bonutti

On page 3 of the Office Action, independent claim 37 and various dependent claims were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,814,073 to Bonutti. Applicants respectfully traverse the rejection. Bonutti does not identically disclose the subject matter recited in claim 37.

Bonutti does not identically disclose the method recited in independent claim 37, including, among other things, a “multi-level nest” that comprises a “first surface contacting the anchor” and a “second surface spaced from the anchor in a direction radially inward relative to the carrier tube,” wherein “the first surface and the second surface are part of an outer surface of the carrier tube.” In the Office Action, the Examiner asserts that the second surface recited in claim 37 is the inner lumen surface of tube 54 in Bonutti. Claim 37 has been amended to recite that the second surface is part of an outer surface of the carrier tube. Accordingly, the Examiner’s argument is no longer applicable.

For the above reasons, Applicants respectfully submit that independent claim 37 and the claims which are dependent thereon are not anticipated by the cited reference and are patentable.

Claim Rejections – 35 U.S.C. § 103(a)***Independent Claims 49, 63, and 71 over Nash et al. in view of Bonutti***

On pages 3-4 of the Office Action, independent claims 49, 63, and 71 and various dependent claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Nash et al. in view of Bonutti. Applicants respectfully traverse the rejection. None of the cited references, alone or in combination, disclose, teach, or suggest the subject matter recited in independent claims 49, 63, or 71.

Independent claim 49

The combination of the cited references would not result in the subject matter recited in independent claim 49. Claim 49 recites a method that includes, among other things, “inserting a tissue puncture closure device into a tissue puncture, the tissue puncture closure device including a carrier tube, a sealing plug, and an anchor, **an outer surface of the carrier tube including a recess that forms a gap between the anchor and the carrier tube in a direction that is transverse to the carrier tube,**” and “moving a tip of an insertion sheath into the recess in the outer surface of the carrier tube.” Neither of the references, alone or in combination, discloses that the outer surface of the carrier tube includes a recess that forms a gap between the anchor and the carrier tube in a direction that is transverse to the carrier tube. Consequently, neither of the references, alone or in combination, discloses moving a tip of an insertion sheath into the recess.

Independent claim 63

The combination of the cited references would not result in the subject matter recited in independent claim 63. Claim 63 recites a method that includes, among other things, “deploying

the anchor by moving a tip of the insertion sheath into a recess in an outer surface of the carrier tube so that the tip is underneath the anchor before the anchor begins to move from an undeployed position.” Neither of the references, alone or in combination, discloses this limitation. If the references were combined in the manner suggested by the Examiner, the insertion sheath of Bonutti would contact the peripheral edge of the anchor of Nash et al. and would not enter a recess in the outer surface so that the tip is underneath the anchor before the anchor begins to move from an undeployed position as recited in claim 63.

Independent claim 71

The combination of the cited references would not result in the subject matter recited in independent claim 71. Claim 71 recites a method that includes, among other things, “inserting a tissue puncture closure device into a tissue puncture, the tissue puncture closure device including a carrier tube, a sealing plug, and an anchor, the carrier tube and the anchor being in contact with each other, **the carrier tube including a recess in an outer surface of the carrier tube, the recess extending underneath the anchor,**” and “positioning a tip of an insertion sheath in the recess so that the tip is between the carrier tube and the anchor.” Neither of the references, alone or in combination, discloses a carrier tube that has a recess in the outer surface that extends underneath the anchor.

For the above reasons, Applicants respectfully submit that independent claims 49, 63, and 71 and the claims which depend therefrom are not obvious in view of the cited references and are patentable.

Independent Claim 67

On page 4 of the Office Action, independent claim 67 and various dependent claims were rejected over U.S. Patent No. 5,282,827 to Kensey et al. in view of Bonutti. Applicants note that the heading states that the rejection is an anticipation rejection in view of Kensey et al. only. However, the rationale for the rejection is focused on combining Kensey et al. with Bonutti. Applicants have treated the rejection as an obviousness rejection over Kensey et al. in view of Bonutti. Applicants respectfully traverse the rejection. None of the cited references, alone or in combination, disclose, teach, or suggest the subject matter recited in independent claim 67.

The combination of the cited references would not result in the subject matter recited in independent claim 67. Claim 67 recites a method that includes, among other things, “inserting a tissue puncture closure device into a tissue puncture, the tissue puncture closure device including a carrier tube, a sealing plug, and an anchor, **the anchor including an indentation that forms a gap between the anchor and the carrier tube, the gap being open along a proximal edge of the anchor**” and “positioning a tip of an insertion sheath in the gap **before the anchor begins to move from an undeployed position.**” Neither of the references, alone or in combination, discloses an anchor having an indentation that forms a gap that is open along a proximal edge of the anchor. The alleged gap in the anchor of Kensey et al. is not open along a proximal edge of the anchor. Kensey et al. does not otherwise include an indentation that forms a gap between the anchor and the carrier tube.

For the above reasons, Applicants respectfully submit that independent claim 67 and the claims which are dependent thereon are not obvious in view of the cited references and are patentable.

Applicants respectfully submit that the present Application is in condition for allowance. Applicants request reconsideration and allowance of the pending claims. The Examiner is invited to contact the undersigned attorney by telephone if the Examiner needs anything or if a telephone interview would advance the prosecution of the present application.

Applicants respectfully put the Examiner and all others on notice that all arguments, representations, and/or amendments contained herein are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application including any patents or patent applications which claim priority to this patent application and/or any patents or patent applications to which priority is claimed by this patent application.

Respectfully submitted,

By

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